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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/606,909	06/29/2000	Ronald J. Pettis	P-4901	7814

7590 01/14/2003

PENNIE & EDMONDS LLP.
1155 AVENUE OF THE AMERICAS
NEW YORK, NY 10036-2711

[REDACTED] EXAMINER

TRAN, BINH Q

ART UNIT	PAPER NUMBER
3748	

DATE MAILED: 01/14/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/606,909	PETTIS ET AL.	
	Examiner	Art Unit	
	BINH Q. TRAN	3748	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on ____ .
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 2-7, 10-30 is/are pending in the application.
- 4a) Of the above claim(s) 17-24 is/are withdrawn from consideration.
- 5) Claim(s) ____ is/are allowed.
- 6) Claim(s) 2-7, 10-16 and 25-30 is/are rejected.
- 7) Claim(s) ____ is/are objected to.
- 8) Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on ____ is/are: a) accepted or b) objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on ____ is: a) approved b) disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. ____ .
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>7-9</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This office action is in response to the amendment filed October 28, 2002.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2-7, 10-16, and 25-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. More specifically,

- In claims 25-30, line 1, "*the administration*" lacks antecedent basis.
- In claims 25-30, line 2, "*the intradermal compartment*" lacks antecedent basis.
- In claim 28, line 3, "*the intradermal space*" lacks antecedent basis.

The claims not specifically mentioned are indefinite since they depended from one of the above claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international

application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 2-7, 10-15, and 25-27 are rejected under 35 U.S.C. 102 (b) as being clearly anticipated by Gross et al. (Gross) (Patent Number 5,848,991).

Regarding claims 2-7, 16, and 25-27, Gross discloses a method for delivering a substance into skin comprising delivering the substance into an intradermal compartment of the human subject's skin, so that the substance is distributed systemically (See col. 6, lines 20-55; Claims 30-32); wherein the needle (14) is selected from the group consisting of microneedles, catheter needles, and injection needles; wherein a single needle is inserted; wherein multiple needles are inserted; wherein the substance is a liquid delivered by pressure directly on the liquid; wherein a hormone, which is selected from the group consisting of insulin and PTH, is delivered (See Figures 1-13; col. 3, lines 9-68; col. 6, lines 20-68; col. 7, lines 1-21).

Regarding claims 10-15, Gross further discloses wherein the outlet is at a depth of about 500 μm to 2 mm when the needle is inserted into the skin, and needle is about 300 μm to 2 mm long (See Figures 1-13; col. 4, lines 10-35; col. 7, lines 37-57).

Regarding claims 28-30, Gross discloses a method for delivering a substance into skin comprising delivering the substance into an intradermal compartment of the human subject's skin via a needle having a length sufficient to penetrate the intradermal space and an outlet at a depth within the intradermal space, so that the substance is distributed systemically; and has a

pharmacokinetic profile similar to subcutaneous delivery of the substance, but with higher plasma levels (See Figures 1-13; col. 3, lines 9-68; col. 6, lines 20-68; col. 7, lines 1-21).

Response to Arguments

Applicants's arguments filed October 28, 2002 have been fully considered but they are not deemed persuasive in part. ***Claims 2-7, 10-16, and 25-30 are pending.***

Applicant's cooperation in amending the claims to overcome the claim objections relating to informalities as well as indefinite claim language is also appreciated.

Applicant's arguments with respect to claims 2-7, 10-16, and 25-30 have been considered but are moot in view of the new ground(s) of rejection as discussed above.

Applicant's amendment (Claims 2-7, 10-16, and 25-30) necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL See MPEP. 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Binh Tran whose telephone number is (703) 305-0245. The examiner can normally be reached on Monday-Friday from 8:30 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas E. Denion, can be reached on (703) 308-2623. The fax phone number for this group is (703) 746-4561.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0861.



BT
January 11, 2003

Binh Tran
Patent Examiner
Art Unit 3748



THOMAS DENION
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700